

**ESCAVITE - sodium fluoride, vitamin a acetate, biotin, magnesium, zinc, copper, calcium pantothenate, folic acid, iron, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, and cyanocobalamin tablet, chewable**

**GM Pharmaceuticals, Inc.**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

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**ESCAVITE™**

**MULTI-VITAMIN WITH IRON AND FLUORIDE 0.25mg CHEWABLE TABLETS**

Nutrition Facts		
Serving Size: 1 Chewable Tablet		
Amount Per Tablet		% Daily Value Adults & Children 4 Years or More
Vitamin A	1000 IU	20%
Vitamin C	100 mg	180%
Vitamin D	400 IU	100%
Vitamin E	30 IU	100%
Thiamine	1.5 mg	100%
Riboflavin	1.7 mg	100%
Niacin	20 mg	100%
Vitamin B6	2 mg	100%
Folic Acid	400 mcg	100%
Vitamin B12	9 mcg	150%
Biotin	45 mcg	15%
Pantothenic Acid	10 mg	100%
Iron	7.5 mg	42%
Magnesium	60 mg	15%
Zinc	7.5mg	50%
Copper	1 mg	50%
Fluoride	0.25 mg	*

\* Daily value not established.

**Ingredient for caries prophylaxis:** \* Fluoride as sodium fluoride.

**Other Ingredients:** Xylitol, microcrystalline cellulose, povidone, magnesium stearate, fruit flavor, talc, sucralose.

**WARNING:** Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. **KEEP THIS PRODUCT OUT OF THE REACH OF CHILDREN.** In case of accidental overdosage, call a doctor or a poison control center immediately.

**ESCAVITE™**

**MULTI-VITAMIN WITH IRON AND FLUORIDE 0.25mg CHEWABLE TABLETS**

**Rx Only**

ESCAVITE - sodium fluoride, vitamin A acetate, ascorbic acid, cholecalciferol, alpha-tocopherol acetate, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, biotin, calcium pantothenate, ferrous fumarate, magnesium oxide, zinc oxide, and cupric oxide tablet, chewable.

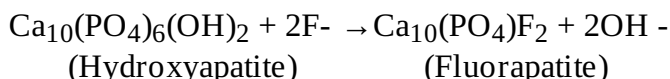
GM Pharmaceuticals, Inc.

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## PHARMACOLOGY

It is well established that fluoridation of the water supply (1 ppm fluoride) during period of tooth development leads to a significant decrease in the incidence of dental caries. Escavite multi-vitamin with Iron and Fluoride Chewable Tablets provide sodium fluoride, magnesium, zinc, copper, twelve essential vitamins, and iron in a chewable tablet. Because tablets are chewable, they provide a topical as well as systemic source of fluoride.

Hydroxyapatite is the principal crystal for all calcified tissue in the human body. The fluoride ion reacts with the hydroxyapatite in the tooth as it is formed to produce the more caries-resistant crystal fluorapatite. The reaction may be expressed by the equation:



Three stages of fluoride deposition in tooth enamel can be distinguished:

1. Small amounts (reflecting the low levels of fluoride in tissue fluids) are incorporated into the enamel crystals while they are being formed.
2. After enamel has been laid down, fluoride deposition continues in the surface enamel. Diffusion of fluoride from the surface inward is apparently restricted.
3. After eruption, the surface enamel acquires fluoride from water, food supplementary fluoride and smaller amounts from saliva.

Escavite multi-vitamin with Iron and Fluoride Chewable Tablets is a prescription product for the dietary management of the metabolic processes of caries prophylaxis, and provides supplementation of the diet with twelve essential vitamins, magnesium, zinc, copper and iron.

Escavite multi-vitamin with Iron and Fluoride 0.25mg Chewable Tablets provide 0.25mg of fluoride in tablet form for children 4-6 years of age where the drinking water contains 0.3 through 0.6 ppm of fluoride.

Escavite multi-vitamin with Iron and Fluoride Chewable Tablets supply significant amounts of Vitamins A, C, D, E, thiamine, riboflavin, niacin, vitamin B6, vitamin B12, folate, biotin, pantothenic acid, magnesium, zinc, copper to supplement the diet, and to help assure that nutritional deficiencies of these vitamins will not develop. Thus, in a single easy-to-use preparation, children obtain twelve essential vitamins and the important minerals, magnesium, zinc, copper, iron, and fluoride.

The American Academy of Pediatrics recommends that children up to the age of 16, in areas where drinking water contains less than optimal levels of fluoride, receive daily fluoride supplementation.

Children using Escavite multi-vitamin with Iron and Fluoride Chewable Tablets regularly should receive semiannual dental examinations. The regular brushing of teeth and attention to good oral hygiene practices are also essential.

## WARNING

Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under

age 6. KEEP THIS PRODUCT OUT OF REACH OF CHILDREN. In case of accidental overdose, call a doctor or Poison Control Center immediately.

Tablets should be chewed or crushed before they are swallowed.

This product is not recommended for children under age 4 due to risk of choking.

## **PRECAUTIONS**

The suggested dose of Escavite multi-vitamin with Iron and Fluoride Chewable Tablets should not be exceeded, since dental fluorosis may result from continued ingestion of large amounts of fluoride.

Before prescribing Escavite multi-vitamin with Iron and Fluoride Chewable Tablets:

1. Determine the fluoride content of the drinking water from all major sources.
2. Make sure the child is not receiving significant amounts of fluoride from other sources such as medications and swallowed toothpaste.
3. Periodically check to make sure that the child does not develop significant dental fluorosis.

Your doctor or dentist is the best source of counsel and guidance in your child's fluoride supplementation.

## **ADVERSE REACTIONS**

Allergic rash and other idiosyncrasies have been rarely reported.

To report adverse side effects or to obtain product information, contact GM Pharmaceuticals at 1-888-535-0305.

## **RECOMMENDED USE**

One tablet daily or as prescribed by doctor, or dentist.

## **DESCRIPTION**

Chewable tablets containing multivitamins with iron and fluoride 0.25mg are sugar free, dye free, off-white speckled, round shape, fruit flavor chewable tablets. Debossed EVT on one side. Available in bottles of 100 tablets.

## **STORAGE**

Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F). See USP Controlled Room Temperature. Protect from light and moisture.

Dispense in a tight, light-resistant container with a child-resistant closure as defined in the USP/NF.

## **REFERENCES**

1. Brudevold F, McCann HG: Fluoride and caries control- Mechanism of action, in Nizel AE, Ed: The Science of Nutrition and its Application in Clinical Dentistry. Philadelphia, WB Saunders Company, 1966, pp 331-347.
2. American Academy of Pediatrics, Committee on Nutrition: Fluoride Supplementation for Children: Interim Policy Recommendations. Pediatrics. 1995; 95 (5):777.
3. American Dental Association Council on Dental Therapeutics. New Fluoride Schedule Adopted. ADA News. May 16, 1994; 12-14.

Manufactured for: GM Pharmaceuticals, Inc. Arlington, TX 76012

Active Ingredient/Active Moiety

<b>Vitamin A Acetate</b> (UNII: 3LE3D9D6OY) (Vitamin A - UNII:81G40H8B0T)	Vitamin A Acetate	1000 [iU]
<b>Biotin</b> (UNII: 6SO6U10H04) (Biotin - UNII:6SO6U10H04)	Biotin	45 ug
<b>Magnesium</b> (UNII: I38ZP9992A) (Magnesium Oxide - UNII:3A3U0GI71G)	Magnesium	60 mg
<b>Zinc</b> (UNII: J41CSQ7QDS) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc	7.4 mg
<b>Copper</b> (UNII: 789U1901C5) (Cupric Oxide - UNII:V1XJQ704R4)	Copper	1 mg
<b>Calcium Pantothenate</b> (UNII: 568ET80C3D) (Calcium Pantothenate - UNII:568ET80C3D)	Calcium Pantothenate	10 mg
<b>Folic Acid</b> (UNII: 935E97BOY8) (Folic Acid - UNII:935E97BOY8)	Folic Acid	0.4 mg
<b>Iron</b> (UNII: E1UOL152H7) (Ferrous Cation - UNII:GW89581OWR)	Iron	7.5 mg
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	100 mg
<b>CHOLECALCIFEROL</b> (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	400 [iU]
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0) (.ALPHA.-TOCOPHEROL - UNII:H4N855PNZ1)	.ALPHA.-TOCOPHEROL ACETATE	30 [iU]
<b>THIAMINE MONONITRATE</b> (UNII: 8K0I04919X) (THIAMINE - UNII:X66NSO3N35)	THIAMINE MONONITRATE	1.5 mg
<b>RIBOFLAVIN</b> (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	1.7 mg
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	20 mg
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	2 mg
<b>CYANOCOBALAMIN</b> (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	9 ug

### Inactive Ingredients

Ingredient Name	Strength
<b>Cellulose, Microcrystalline</b> (UNII: OP1R32D61U)	
<b>Xylitol</b> (UNII: VCQ006KQ1E)	
<b>Sucralose</b> (UNII: 96K6UQ3ZD4)	
<b>Magnesium Stearate</b> (UNII: 70097M6I30)	
<b>Talc</b> (UNII: 7SEV7J4R1U)	
<b>Povidone</b> (UNII: FZ989GH94E)	

### Product Characteristics

<b>Color</b>	WHITE (Off-white, speckled)	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	16mm
<b>Flavor</b>	FRUIT	<b>Imprint Code</b>	EVT
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58809-888-01	100 in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		02/01/2012	

**Labeler** - GM Pharmaceuticals, Inc. (793000860)

